Indications for Implantable Cardioverter Defibrillators

FDA HEARING
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representing NASPE

NASPE: North American Society for Pacing and Electrophysiology

- Professional organization of 3500 physicians, scientists, and health professionals expert in the study and management of patients with cardiac rhythm disorders.
- NASPE's mission is to improve the care of patients by promoting research, education, and training and providing leadership toward optimal health care policies and standards.

NASPE

Each year approximately:

- 100,000 patients undergo pacemaker implantation
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- 30,000 receive an implantable cardiac defibrillator
- and over 50,000 undergo an electrophysiology study.
- Most of these procedures are performed by NASPE members.

NASPE Supports the FDA Proposed Revision to the Indications For ICD Use Which is Under Consideration

- "The implantable cardioverter defibrillator is intended to provide (ventricular antitachycardia pacing and) ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias."
- The FDA would not state which patients are at risk for life-threatening ventricular arrhythmias

Current Indications For ICD Use

- The implantable cardiac defibrillator (ICD) is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:
  - Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia; or
  - Recurrent, poorly tolerated, sustained ventricular tachycardia."

Current Indications For ICD Use

- Guidant, has indications for an additional patient population based on the results of the MADIT study:
  - Prior MI, LVEF ≤35%, documented episode of NSVT with an inducible tachyarrhythmia.
  - Patients suppressible with IV procainamide or an equivalent antiarrhythmic haven not been studied

NASPE Agrees with the FDA Rationale For Proposed Change In Indications For Use

- Current indications for use are not consistent with current practice which is based on clinical information which is widely available and which forms the basis for current practice.
- NASPE feels it would be more accurate if the ICDs stated indication is for the device's known functionality, and does not attempt to define the population at risk
- Precedent for use of general functional indications exists for coronary balloon angioplasty catheters and heart valves.

AVID Trial

Objective: Determine the relative efficacy of ICD versus antiarrhythmic drug therapy in patients with aborted sudden death or hemodynamically unstable VT.

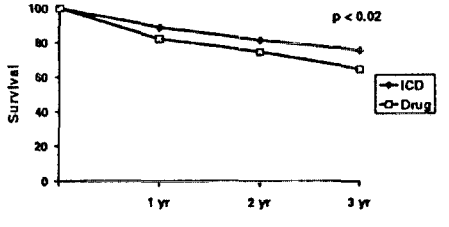
Study Design: Multicenter randomized parallel group study in 1016 patients (prematurely terminated).

Entry Criterion and Rx:
Aborted SCD, sustained VT with syncope, or hemodynamically unstable VT with EF < 40%.
Rx with ICD or empiric amio or guided sotolol.

Patient Population:
age 65 years, EF 31%, CAD in 81%, SCD in 45%

NEJM 1997; 337: 1576-83

AVID



39% reduction mort 1 yr, 31% at 3 yrs

NEJM 1997; 337: 1576-83

AVID Registry

- 5989 patients screened, 1016 randomized
- 4595 followed in a registry

Registry results:
4595 followed in registry
4219 registry patients enrolled before 1997 followed through the national health index

Mortality rates at 16.9±11.5 months of follow-up

• VF cardiac arrest	238 / 1399	(17.0%)
• Syncopal VT	598/127	(21.2%)
• Symptomatic VT	168 / 1065	(15.8%)
• Stable VT	98 / 497	(19.7%)
• VT/VF with transient cause	48/270	(17.8%)
• Syncope	48/390	(12.3%)

Conclusion:
Patients seemingly at lower-risk of ventricular arrhythmias have a high mortality similar to that of higher risk AVID eligible patients.

Circ 1999; 99: 1692-1699

Outcome of patients With Nonischemic Dilated Cardiomyopathy and Unexplained Syncope Treated with an Implantable Defibrillator

Knight, Morady et al., JACC 1999; 33:1964-70.

- 14 pts with syncope, nonischemic CM, neg EP, rx'd with ICD
- 19 pts with cardiac arrest, nonischemic CM, rx'd with ICD (control group)

- 7 / 14 (50%) in syncope group received appropriate ICD shock during 24+14 m fu
- 8 / 19 (42%) in arrest group received appropriate ICD shock

Conclusion: These results support ICD implantation in pts with IDC, unexplained syncope , and negative EPS

Long-Term Follow-Up of patients With Long-QT Syndrome Treated With Beta-Blockers and Continuous Pacing

Parvin Dorostkar, Eldar Michael, Belhassen, Scheinman MM.
Circ 1999: 100: 2431-2436.

- 37 pts with LQTS treated with pacing & BB Rx
- 6.3+/-4.6 yrs follow-up
- 32 women, 5 men, 32 years
- 23 failed BB alone

- 3 died from a presumed arrhythmia during f/u
- 3 other pts had ASD during fu
- over 6.3 yrs 24% incidence of SCD or ASD (17% in compliant pts)

Conclusion: Combination therapy in LQTS patients results in an unacceptably high risk of potential fatal arrhythmias during fu.

Rationale for NAPE's Support of the Proposal

- Recognizes that the decision to implant an ICD is a medical decision made by patients and their physicians.
- A decision to recommend ICD placement is based on the most current clinical evidence which continues to evolve as more informaiton becomes available.
- The ACC/AHA and NASPE publish guidelines on the indications for ICD and PPM implantation which are updates on a regular basis.
- These guidelines also prevent over use by the medical community.